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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application

Applicants

Abraham Pinter et al.

Application No.

10/628,004

Confirmation No.

3975

Filed

: July 25, 2003

For

USE OF TRANSGENIC MICE FOR THE

EFFICIENT ISOLATION OF NOVEL HUMAN

MONOCLONAL ANTIBODIES WITH

NEUTRALIZING ACTIVITY AGAINST PRIMARY

HIV-1 STRAINS AND NOVEL HIV-1 NEUTRALIZING ANTIBODIES

Group Art Unit

1645

Examiner

Not Yet Assigned

New York, New York 10020

March 3, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure Statement in the above-identified application. This Statement is submitted:

- [] within three months of the application filing date;
- [X] more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

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Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants make of record the

following documents:*

U.S. Patents

Applicant

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Issue Date

Chang et al.

5,266,478

November 30, 1993

^{*} A complete Form PTO-1449 listing these documents is attached hereto.

Foreign Publications

WO 95/24904 September 21, 1995 WO 96/34096 October 31, 1996 WO 99/12556 March 18, 1999

Other Documents

Alsmadi, O. et al., "Antibody-Dependent Cellular Cytotoxicity Directed against Cells Expressing Human Immunodeficiency Virus Type 1 Envelope of Primary or Laboratory-Adapted Strains by Human and Chimpanzee Monoclonal Antibodies of Different Epitope Specificities," J. Virol., 72:286-293 (1998)

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Binley, J.M. et al., "An Investigation of the High-Avidity Antibody Response to Glycoprotein 120 of Human Immunodeficiency Virus Type 1," *AIDS Research and Human Retroviruses*, 13:1007-1015 (1997)

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Ditzel, H.J. et al., "Mapping the Protein Surface of Human Immunodeficiency Virus Type 1 gp120 using Human Monoclonal Antibodies from Phage Display Libraries," *J. Mol. Biol.*, 267:684-695 (1997)

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D'Souza, P.M. et al., "Evaluation of Monoclonal Antibodies to Human Immunodeficiency Virus Type 1 Primary Isolates by Neutralization Assays: Performance Criteria for Selecting Candidate Antibodies for Clinical Trials," *The Journal of Infectious Diseases*, 175:1056-1062 (1997)

Fontenot, J.D. et al., "Presentation of HIV V3 Loop Epitopes for Enhanced Antigenicity, Immunogenicity and Diagnostic Potential," AIDS, 9:1121-1129 (1995)

Forthal, D.N. et al., "Functional Activities of 20 Human Immunodeficiency Virus Type 1 (HIV-1)-Specific Human Monoclonal Antibodies," *AIDS Research and Human Retroviruses*, 11:1095-1099 (1995)

Fouts, T.R. et al., "Neutralization of the Human Immunodeficiency Virus Type 1 Primary Isolate JR-FL by Human Monoclonal Antibodies Correlates with Antibody Binding to the Oligomeric Form of the Envelope Glycoprotein Complex," *J. Virol.*, 71:2779-2785 (1997)

Fung, M.S.C. et al, "Identification and Characterization of a Neutralization Site Within the Second Variable Region of Human Immunodeficiency Virus Type 1 gp120," *J. Virol.*, 66:848-856 (1992)

Gauduin, M.-C. et al., "Effective Ex Vivo Neutralization of Human Immunodeficiency Virus Type 1 in Plasma by Recombinant Immunoglobulin Molecules," *J. Virol.*, 70:2586-2592 (1996)

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Gorny, M.K. et al., "Repertoire of Neutralizing Human Monoclonal Antibodies Specific for the V3 Domain of HIV-1 gp120," J. Immunol., 150:635-643 (1993)

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Gorny, M.K. et al., "Human Monoclonal Antibodies to the V3 Loop of HIV-1 With Intra- and Interclade Cross-Reactivity," *J. Immunol.*, 159:5114-5122 (1997)

Gorny, M.K. et al., "A Human Monoclonal Antibody Specific for the V3 Loop of HIV Type 1 Clade E Cross-Reacts with Other HIV Type 1 Clades," *AIDS Research and Human Retroviruses*, 14:213-221 (1998)

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Hill, M.C. et al., "Envelope Glycoproteins from Human Immunodeficiency Virus Types 1 and 2 and Simian Immunodeficiency Virus Can Use Human CCR5 as a Coreceptor for Viral Entry and Make Direct CD4-Dependent Interactions with This Chemokine Receptor," *J. Virol.*, 71:6296-6304 (1997)

Karwowska, S. et al., "Type-Specific' Human Monoclonal Antibodies Cross-React with the V3 Loop of Various HIV-1 Isolates," *Vaccines 92*, 171-174 (1992)

Kayman, S.C. et al., "Presentation of Native Epitopes in the V1/V2 and V3 Regions of Human Immunodeficiency Virus Type 1 gp120 by Fusion Glycoproteins Containing Isolated gp120 Domains," *J. Virol.*, 68:400-410 (1994)

Krachmarov, C.P. et al., "V-3 Specific Polyclonal Antibodies Affinity Purified from Sera of Infected Humans Effectively Neutralize Primary Isolates of Human Immunodeficiency Virus Type 1," *AIDS Research and Human Retroviruses*, 17:1737-1748 (2001)

LaCasse, R.A. et al., "Fusion-Competent Vaccines: Broad Neutralization of Primary Isolates of HIV," *Science*, 283:357-362 (1999)

Laisney, I.L. et al., "Dual Specificity of a Human Neutralizing Monoclonal Antibody, Specific for the V3 Loop of GP120 (HIV-1)," *Immunology Letters*, 67:185-192 (1999)

Little, M. et al., "Of Mice and Men: Hybridoma and Recombinant Antibodies," *Immunology Today*, 21:364-370 (2000)

McKeating, J.A. et al., "Chimeric Viruses Expressing Primary Envelope Glycoproteins of Human Immunodeficiency Virus Type 1 Show Increased Sensitivity to Neutralization by Human Sera," *Virology*, 220:450-460 (1996)

Mondor, I. et al., "Human Immunodeficiency Virus Type 1 Attachment to HeLa CD4 Cells Is CD4 Independent and gp120 Dependent and Requires Cell Surface Heparans," *J. Virol.*, 72:3623-3634 (1998)

Moore, J.P. et al., "Immunochemical Analysis of the gp120 Surface Glycoprotein of Human Immunodeficiency Virus Type 1: Probing the Structure of the C4 and V4 Domains and the Interaction of the C4 Domain with the V3 Loop," *J. Virol.*, 67:4785-4796 (1993)

Moore, J.P. et al., "Probing the Structure of the V2 Domain of Human Immunodeficiency Virus Type 1 Surface Glycoprotein gp120 with a Panel of Eight Monoclonal Antibodies: Human Immune Response to the V1 and V2 Domains," *J. Virol.*, 67:6136-6151 (1993)

Moore, J.P. et al., "Development of the Anti-gp120 Antibody Response During Seroconversion to Human Immunodeficiency Virus Type 1," *J. Virol.*, 68:5142-5155 (1994)

- Moore, J.P. et al., "Exploration of Antigenic Variation in gp120 From Clades A Through F of Human Immunodeficiency Virus Type 1 by Using Monoclonal Antibodies," J. Virol., 68:8350-8364 (1994)
- Moore, J.P. et al., "HIV-1 Neutralization: the Consequence of Viral Adaptation to Growth on Transformed T Cells," AIDS, 9:S117-S136 (1995)
- Moore, J.P. et al., "A Human Monoclonal Antibody to a Complex Epitope in the V3 Region of gp120 of Human Immunodeficiency Virus Type 1 Has Broad Reactivity Within and Outside Clade B," J. Virol., 69:122-130 (1995)
- Moore, J.P. et al., "Antibody Cross-Competition Analysis of the Human Immunodeficiency Virus Type 1 gp120 Exterior Envelope Glycoprotein," *J. Virol.*, 70:1863-1872 (1996)
- Murakami, T. et al., "Inhibitory Mechanism of the CXCR4 Antagonist T22 against Human Immunodeficiency Virus Type 1 Infection," J. Virol., 73:7489-7496 (1999)
- Nyambi, P.N. et al., "Mapping of Epitopes Exposed on Intact Human Immunodeficiency Virus Type 1 (HIV-1) Virions: a New Strategy for Studying the Immunologic Relatedness of HIV-1," J. Virol., 72:9384-9391 (1998)
- Pal, R. et al., "Characterization of a Neutralizing Monoclonal Antibody to the External Glycoprotein of HIV-1," *Intervirology*, 86:86-93 (1992)
- Parren, P.W. H. et al., "Antibodies against HIV-1 from Phage Display Libraries: Mapping of an Immune Response and Progress Towards Antiviral Immunotherapy," *Chemical Immunology*, 65:18-56 (1997)
- Parren, P.W. H. et al., "Erratum to 'Relevance of the Antibody Response Against Human Immunodeficiency Virus Type 1 Envelope to Vaccine Design'," *Immunology Letters*, 58:125-132 (1997)
- Parren, P.W. H. et al., "Neutralization of Human Immunodeficiency Virus Type 1 by Antibody to gp120 Is Determined Primarily by Occupancy of Sites on the Virion Irrespective of Epitope Specificity," *J. Virol.*, 72:3512-3519 (1998)
- Pinter, A. et al., "A Potent, Neutralizing Human Monoclonal Antibody Against a Unique Epitope Overlapping the CD4 Binding Site of HIV-1 gp120 That is Broadly Conserved Across North American and African Virus Isolates," *AIDS Research and Human Retroviruses*, 9:985-996 (1993)
- Pinter, A. et al., "Potent Neutralization of Primary HIV-1 Isolates by Antibodies Directed Against Epitopes Present in the V1/V2 Domain of HIV-1 gp120," *Vaccine*, 16:1803-1811 (1998)
- Robinson, J.E. et al., "Identification of Conserved and Variant Epitopes of Human Immunodeficiency Virus Type 1 (HIV-1) gp120 by Human Monoclonal Antibodies Produced by EBV-Transformed Cell Lines," *AIDS Research and Human Retroviruses*, 6:567-579 (1990)

Sattentau, Q.J., "Conservation of HIV-1 gp120 Neutralizing Epitopes After Formalin Inactivation," AIDS, 9:1383-1385 (1995)

Schnierle, B.S. et al., "Pseudotyping of Murine Leukemia Virus with the Envelope Glycoproteins of HIV Generates a Retroviral Vector with Specificity of Infection for CD4-Expressing Cells," *Proc. Natl. Acad. Sci.*, 94:8640-8645 (1997)

Schutten, M. et al., "Characterization of a V3 Domain-Specific Neutralizing Human Monoclonal Antibody that Preferentially Recognizes Non-Syncytium-Inducing Human Immunodeficiency Virus Type 1 Strains," *Journal of General Virology*, 76:1665-1673 (1995)

Schutten, M. et al., "Enhancement of Infectivity of a Non-Syncytium Inducing HIV-1 by sCD4 and by Human Antibodies that Neutralize Syncytium-Inducing HIV-1," *Scand. J. Immunol.*, 41:18-22 (1995)

Schutten, M. et al., "Human Antibodies that Neutralize Primary Human Immunodeficiency Virus Type 1 in vitro Do Not Provide Protection in an in vivo Model," Journal of General Virology, 77:1667-1675 (1996)

Schutten, M. et al., "Modulation of Primary Human Immunodeficiency Virus Type 1 Envelope Glycoprotein-Mediated Entry by Human Antibodies," *Journal of General Virology*, 78:999-1006 (1997)

Scott, C.F. et al., "Human Monoclonal Antibody That Recognizes the V3 Region of Human Immunodeficiency Virus gp120 and Neutralizes the Human T-Lymphotropic Virus Type III_{MN} Strain," *Proc. Natl. Acad. Sci.*, 87:8597-8601 (1990)

Seligman, S.J. et al., "Characterization by Serial Deletion Competition ELISAs of HIV-1 V3 Loop Epitopes Recognized by Monoclonal Antibodies," *Molecular Immunology*, 33:737-745 (1996)

Stamatatos, L. et al., "An Envelope Modification That Renders a Primary, Neutralization-Resistant Clade B Human Immunodeficiency Virus Type 1 Isolate Highly Susceptible to Neutralization by Sera from Other Clades," *J. Virol.*, 72:7840-7845 (1998)

Sullivan, N. et al., "Determinants of Human Immunodeficiency Virus Type 1 Envelope Glycoprotein Activation by Soluble CD4 and Monoclonal Antibodies," *J. Virol.*, 72:6332-6338 (1998)

Thall, M. et al., "Characterization of Conserved Human Immunodeficiency Virus Type 1 gp120 Neutralization Epitopes Exposed Upon gp120-CD4 Binding," J. Virol., 67:3978-3988 (1993)

Tilley, S.A. et al., "Synergistic Neutralization of HIV-1 by Human Monoclonal Antibodies Against the V3 Loop and the CD4-Binding Site of gp120," AIDS Research and Human Retroviruses, 8:461-467 (1992)

Trkola, A. et al., "Cross-Clade Neutralization of Primary Isolates of Human Immunodeficiency Virus Type 1 by Human Monoclonal Antibodies and Tetrameric CD4-IgG," J. Virol., 69:6609-6617 (1995)

Trkola, A. et al., "CD4-Dependent, Antibody-Sensitive Interactions Between HIV-1 and Its Co-receptor CCR-5," *Nature*, 384:184-187 (1996)

Trkola, A. et al., "Human Monoclonal Antibody 2G12 Defines a Distinctive Neutralization Epitope on the gp120 Glycoprotein of Human Immunodeficiency Virus Type 1," J. Virol., 70:1100-1108 (1996)

Tykola, A. et al., "Neutralization Sensitivity of Human Immunodeficiency Virus Type 1 Primary Isolates to Antibodies and CD4-Based Reagents Is Independent of Coreceptor Usage," J. Virol., 72:1876-1885 (1998)

Ugolini, S. et al., "Inhibition of Virus Attachment to CD4⁺ Target Cells Is a Major Mechanism of T Cell Line-Adapted HIV-1 Neutralization," *J. Exp. Med.*, 186:1287-1298 (1997)

VanCott, T.C. et al., "Dissociation Rate of Antibody-gp120 Binding Interactions Is Predictive of V3-Mediated Neutralization of HIV-1," *J. Immunol.*, 153:449-459 (1994)

van Spriel, A.B., "Immunotherapeutic Perspective for Bispecific Antibodies," *Immunology Today*, 21:391-397 (2000).

Wu, D. et al., "Neuroprotection With Noninvasive Neurotrophin Delivery to the Brain," *Proc. Natl. Acad. Sci. USA*, 96:254-259 (1999).

Wu, L. et al., "CD4-Induced Interaction of Primary HIV-1 gp120 Glycoproteins With the Chemokine Receptor CCR-5," *Nature*, 384:179-183 (1996)

Yang, G. et al., Neutralizing Antibodies Against HIV Determined by Amplification of Viral Long Terminal Repeat Sequences From Cells Infected in Vitro by Nonneutralized Virions," *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, 17:27-34 (1998)

Zolla-Pazner, S. et al., "Neutralization of a Clade B Primary Isolate by Sera from Human Immunodeficiency Virus —Uninfected Recipients of Candidate AIDS Vaccines," J. Infec. Diseases., 175:764-774 (1997)

Zolla-Pazner, S. et al., "Immunotyping of Human Immunodeficiency Virus Type 1 (HIV): an Approach to Immunologic Classification of HIV," *J. Virol.*, 73:4042-4051 (1999)

Applicants respectfully request that the above documents be (1) fully considered by the Examiner during the course of the examination of this application and (2) printed on any patent issuing from this application. Applicants also request that a copy of the enclosed Form PTO-1449 duly initialed by the Examiner be forwarded to the undersigned with the next communication.

Respectfully submitted,

Jane T. Gunnison (Reg. No. 38,479) Stanley D. Liang (Reg. No. 43,753)

Attorneys for Applicants

R. Minako Pazdera (Reg. No. 46,984)

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FORM PTO-1449

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,266,478	11/30/1993	Chang et al.	435	240.27	

FOREIGN PATENT DOCUMENTS

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INITIAL	NUMBER	DAIL	COUNTRI	CLASS	SUBULASS	YES	NO
	WO 95/24904	09/21/1995	PCT				
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
	Alsmadi, O. et al., "Antibody-Dependent Cellular Cytotoxicity Directed against Cells Expressing Human Immunodeficiency Virus Type 1 Envelope of Primary or Laboratory-Adapted Strains by Human and Chimpanzee Monoclonal Antibodies of Different Epitope Specificities," <i>J. Virol.</i> , 72:286-293 (1998)
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	Conley, A.J. et al., "Neutralization of Divergent Human Immunodeficiency Virus Type 1 Variants and Primary Isolates by IAM-41-2F5, an Anti-gp41 Human Monoclonol Antibody," <i>Proc. Natl. Acad. Sci.</i> , 91:3348-3352 (1994)

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	D'Souza, P.M. et al., "Neutralization of Primary HIV-1 Isolates by Anti-Envelope Monoclonal Antibodies," <i>AIDS</i> , 9:867-874 (1995)
	D'Souza, P.M. et al., "Evaluation of Monoclonal Antibodies to Human Immunodeficiency Virus Type 1 Primary Isolates by Neutralization Assays: Performance Criteria for Selecting Candidate Antibodies for Clinical Trials," <i>The Journal of Infectious Diseases</i> , 175:1056-1062 (1997)
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- Carre	·		
	Krachmarov, C.P. et al., "V-3 Specific Polyclonal An Humans Effectively Neutralize Primary Isolates of H Research and Human Retroviruses, 17:1737-1748 (luman Immunodeficiency \	om Sera of Infected /irus Type 1," AIDS
	LaCasse, R.A. et al., "Fusion-Competent Vaccines: Science, 283:357-362 (1999)	Broad Neutralization of Pr	imary Isolates of HIV,"
	Laisney, I.L. et al., "Dual Specificity of a Human Neu Loop of GP120 (HIV-1)," <i>Immunology Letters</i> , 67:18	utralizing Monoclonal Antib 35-192 (1999)	oody, Specific for the V3
	Little, M. et al., "Of Mice and Men: Hybridoma and F 21:364-370 (2000).	Recombinant Antibodies," /	mmunology Today,
	McKeating, J.A. et al., "Chimeric Viruses Expressing Immunodeficiency Virus Type 1 Show Increased Se <i>Virology</i> , 220:450-460 (1996)		
	Mondor, I. et al., "Human Immunodeficiency Virus T Independent and gp120 Dependent and Requires C (1998)	ype 1 Attachment to HeLa cell Surface Heparans," <i>J</i> .	CD4 Cells Is CD4 Virol., 72:3623-3634
	Moore, J.P. et al., "Immunochemical Analysis of the Immunodeficiency Virus Type 1: Probing the Structuof the C4 Domain with the V3 Loop," <i>J. Virol.</i> , 67:47:	ire of the C4 and V4 Doma	
	Moore, J.P. et al., "Probing the Structure of the V2 E Surface Glycoprotein gp120 with a Panel of Eight M to the V1 and V2 Domains," <i>J. Virol.</i> , 67:6136-6151	onoclonal Antibodies: Hun	deficiency Virus Type 1 nan Immune Response
	Moore, J.P. et al., "Development of the Anti-gp120 A Human Immunodeficiency Virus Type 1," J. Virol., 6		Seroconversion to
	Moore, J.P. et al., "Exploration of Antigenic Variation Immunodeficiency Virus Type 1 by Using Monoclona		
	Moore, J.P. et al., "HIV-1 Neutralization: the Conseq Transformed T Cells," AIDS, 9:S117-S136 (1995)	uence of Viral Adaptation	to Growth on
-	Moore, J.P. et al., "A Human Monoclonal Antibody to Human Immunodeficiency Virus Type 1 Has Broad I 69:122-130 (1995)	o a Complex Epitope in the Reactivity Within and Outs	e V3 Region of gp120 of ide Clade B," <i>J. Virol.</i> ,
	Moore, John P. et al., "Antibody Cross-Competition Type 1 gp120 Exterior Envelope Glycoprotein," <i>J. Vi</i>	Analysis of the Human Imr <i>irol</i> ., 70:1863-1872 (1996)	nunodeficiency Virus
<u> </u>	Murakami, T. et al., "Inhibitory Mechanism of the CX Immunodeficiency Virus Type 1 Infection," <i>J. Virol.</i> , 7		nst Human
	Nyambi, P.N. et al., "Mapping of Epitopes Exposed (HIV-1) Virions: a New Strategy for Studying the Imr 72:9384-9391 (1998)		
	Pal, R. et al., "Characterization of a Neutralizing Mor HIV-1," <i>Intervirology</i> , 86:86-93 (1992)	noclonal Antibody to the E	xternal Glycoprotein of
	Parren, P.W. H. et al., "Antibodies against HIV-1 from Response and Progress Towards Antiviral Immunot		
	Parren, P.W. H. et al., "Erratum to 'Relevance of the Immunodeficiency Virus Type 1 Envelope to Vaccine (1997)		

DATE CONSIDERED

EXAMINER

FORM PTO-144	9 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. ABX-PHRI CON	APPLN. NO. 10/628,004
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MAR 0 8 2004 E		FILING DATE July 25, 2003	GROUP 1645
CATEMAT & TRACE			
	Parren, P.W. H. et al., "Neutralization of Human Imm Is Determined Primarily by Occupancy of Sites on the Virol., 72:3512-3519 (1998)		
	Pinter, A. et al., "A Potent, Neutralizing Human Mond Overlapping the CD4 Binding Site of HIV-1 gp120 TI and African Virus Isolates," AIDS Research and Hum	hat is Broadly Conserved	Across North American
	Pinter, A. et al., "Potent Neutralization of Primary HIV Epitopes Present in the V1/V2 Domain of HIV-1 gp1:		
	Robinson, J.E. et al., "Identification of Conserved an Virus Type 1 (HIV-1) gp120 by Human Monoclonal A Lines," AIDS Research and Human Retroviruses, 6:	Antibodies Produced by El	
	Sattentau, Q.J., "Conservation of HIV-1 gp120 Neutr <i>AIDS</i> , 9:1383-1385 (1995)	ralizing Epitopes After For	malin Inactivation,"
	Schnierle, B.S. et al., "Psuedotyping of Murine Leuk Generates a Retroviral Vector with Specificity of Infe Sci., 94:8640-8645 (1997)		
	Schutten, M. et al., "Characterization of a V3 Domain Antibody that Preferentially Recognizes Non-Syncyti Type 1 Strains," <i>Journal of General Virology</i> , 76:166	ium-Inducing Human Immi	
	Schutten, M. et al., "Enhancement of Infectivity of a Human Antibodies that Neutralize Syncytium-Inducir		
	Schutten, M. et al., "Human Antibodies that Neutraliz in vitro Do Not Provide Protection in an in vivo Mode (1996)		
	Schutten, M. et al., "Modulation of Primary Human Ir Glycoprotein-Mediated Entry by Human Antibodies,"		
	Scott, C.F. et al., "Human Monoclonal Antibody That Immunodeficiency Virus gp120 and Neutralizes the I Proc. Natl. Acad. Sci., 87:8597-8601 (1990)		
	Seligman, S.J. et al., "Characterization by Serial Del Epitopes Recognized by Monoclonal Antibodies," Mo		
	Stamatatos, L. et al., "An Envelope Modification Tha Clade B Human Immunodeficiency Virus Type 1 Isol from Other Clades," <i>J. Virol.</i> , 72:7840-7845 (1998)		
	Sullivan, N. et al., "Determinants of Human Immunoo Activation by Soluble CD4 and Monoclonal Antibodie		
	Thall, M. et al., "Characterization of Conserved Hum Neutralization Epitopes Exposed Upon gp120-CD4 E		
	Tilley, S.A. et al., "Synergistic Neutralization of HIV-1 V3 Loop and the CD4-Binding Site of gp120," <i>AIDS</i> (1992).		
1			

EXAMINER

DATE CONSIDERED

Trkola, A. et al., "Cross-Clade Neutralization of Primary Isolates of Human Immunodeficiency Virus Type 1 by Human Monoclonal Antibodies and Tetrameric CD4-IgG," *J. Virol.*, 69:6609-6617 (1995)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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	APPLICANT Abraham Pinter et al.	CONFIRMATION NO. 3975
	FILING DATE July 25, 2003	GROUP 1645

 Trkola, A. et al., "CD4-Dependent, Antibody-Sensitive Interactions Between HIV-1 and Its Co-receptor CCR-5," <i>Nature</i> , 384:184-187 (1996)
Trkola, A. et al., "Human Monoclonal Antibody 2G12 Defines a Distinctive Neutralization Epitope on the gp120 Glycoprotein of Human Immunodeficiency Virus Type 1," <i>J. Virol.</i> , 70:1100-1108 (1996)
Tykola, A. et al., "Neutralization Sensitivity of Human Immunodeficiency Virus Type 1 Primary Isolates to Antibodies and CD4-Based Reagents Is Independent of Coreceptor Usage," <i>J. Virol.</i> , 72:1876-1885 (1998)
Ugolini, S. et al., "Inhibition of Virus Attachment to CD4 ⁺ Target Cells Is a Major Mechanism of T Cell Line-Adapted HIV-1 Neutralization," <i>J. Exp. Med.</i> , 186:1287-1298 (1997)
VanCott, T.C. et al., "Dissociation Rate of Antibody-gp120 Binding Interactions Is Predictive of V3-Mediated Neutralization of HIV-1," <i>J. Immunol.</i> , 153:449-459 (1994)
van Spriel, A.B., "Immunotherapeutic Perspective for Bispecific Antibodies," <i>Immunology Today</i> , 21:391-397 (2000).
Wu, D. et al., "Neuroprotection With Noninvasive Neurotrophin Delivery to the Brain," <i>Proc. Natl. Acad Sci.</i> , 96:254-259 (1999).
Wu, L. et al., "CD4-Induced Interaction of Primary HIV-1 gp120 Glycoproteins With the Chemokine Receptor CCR-5," <i>Nature</i> , 384:179-183 (1996)
Yang, G. et al., Neutralizing Antibodies Against HIV Determined by Amplification of Viral Long Terminal Repeat Sequences From Cells Infected in Vitro by Nonneutralized Virions," <i>Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology</i> , 17:27-34 (1998)
Zolla-Pazner, S. et al., "Neutralization of a Clade B Primary Isolate by Sera from Human Immunodeficiency Virus —Uninfected Recipients of Candidate AIDS Vaccines," <i>J. Infec. Diseases.</i> , 175:764-774 (1997)
Zolla-Pazner, S. et al., "Immunotyping of Human Immunodeficiency Virus Type 1 (HIV): an Approach to Immunologic Classification of HIV," <i>J. Virol.</i> , 73:4042-4051 (1999)

EXAMINER

DATE CONSIDERED